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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Susumu MUTO et al.

Group Art Unit: Not Yet Assigned

Appl. No.

: 10/516,293

(U.S. National Stage of PCT/JP03/07128)

I.A. Filed

: June 5, 2003

**Examiner: Not Yet Assigned** 

For

: REMEDIES FOR NEURODEGENERATIVE DISEASES

#### INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop AMENDMENT
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and §§1.97-1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited and discussed in the specification, and the International Search Report issued in connection with International Patent Application No. PCT/JP03/07128, which published as WO 03/103657 A1 on December 18, 2003, of which the present application is the U.S. National Stage Application. Copies of the International Search Report (in English and Japanese), Written Opinion (in Japanese), and International Preliminary Examination Report (in Japanese) were enclosed with the papers when entering the National Stage on December 8, 2004. Applicants enclose herewith a copy of the International Preliminary Examination Report in English. The following is a list of the documents cited in the above-noted documents:

XU, et al., "The Journal of Neuroscience," 2001, Vol. 21, No.1, RC118, 5 pages, Applicants note that this document is cited on pages 1 and 2 of the specification of the present application;

AISEN, "Journal of Pain and Symptom Management," 2002, Vol. 23, No. 4, page S35-40, Applicants note that this document is cited on page 2 of the specification of the present application;

KANG, et al., "Neuroreport," 2001, Vol. 12, No.7, page 1449-1452, Applicants note that this document is cited on page 2 of the specification of the present application;

YAMAMOTO, et al., "The Journal of Clinical Investigation," 2001, Vol. 107, No. 2, page 135-142, Applicants note that this document is cited on page 2 of the specification of the present application;

MATTSON, et al., "The Journal of Clinical Investigation," 2001, Vol. 107, No. 3, page 247-254, Applicants note that this document is cited on page 2 of the specification of the present application;

MATTSON, et al., "Cell and Tissue Research," 2000, Vol. 301, No. 1, page 173-187, Applicants note that this document is cited on page 2 of the specification of the present application;

MILLET, et al., "The Journal of Biological Chemistry," 2000, Vol. 275, No. 20, page 15114-15121, Applicants note that this document is cited on page 2 of the specification of the present application;

KONTA, et al., "The Journal of Biological Chemistry," 2001, Vol. 276, No. 16, page 12697-12701, Applicants note that this document is cited on page 2 of the specification of the present application;

PIU, et al., "Molecular and Cellular Biology," 2001, Vol. 21, No. 9, page 3012-3024, Applicants note that this document is cited on page 2 of the specification of the present application;

ISHIGE, et al., "Yakugaku Zasshi," 1999, Vol. 119, No. 7, page 510-518, Applicants note that this document is cited on page 2 of the specification of the present application;

WON, et al., "Neuroscience," 1999, Vol. 94, No.1, page 83-91, Applicants note that this document is cited on page 2 of the specification of the present application;

WO 99/65449, Applicants note that this document is cited on page 3 of the specification of the present application;

European Patent Publication No. EP 1 314 712, together with family member WO 02/076918 and U.S. Patent Publication No. 2004/122244 A1. Applicants note that the International Patent Publication is cited on page 3 of the specification of the present application;

European Patent Publication No. EP 1 344 525, together with family member WO 02/051397 and U.S. family member 2004/048891 A1. Applicants note that the International Patent Publication is cited on pages 3 and 7 of the specification of the present application;

European Patent Publication No. EP 1 352 650, together with family member WO 02/49632 and U.S. Patent Publication No. 2004/259877 A1. Applicants note that the International Patent Publication is cited on page 3 of the specification of the present application;

European Patent Publication No. EP 0 221 211, together with family member Japanese Laid-open Patent Publication No. SHO 62-99329 and U.S. family members 4,560,549, 4,725,590 and U.S. 4,742,083. Applicants note that both documents are cited on page 3 of the specification of the present application;

U.S. Patent No. 6,117,859, Applicants note that this document is cited on page 3 of the specification of the present application;

MACIELAG, et al., "The Journal of Medicinal Chemistry," 1998, Vol. 41, No.16 page 2939-2945, Applicants note that this document is cited on page 102 of the specification of the present application;

WAISSER, et al., "Archiv der Pharmazie," 1998, Vol. 331, No.1, page 3-6, Applicants note that this document is cited on page 102 of the specification of the present application;

FRAME, et al., "The Biochemical Journal," 2001, Vol. 359, No. PT1, page 1-16, Applicants note that this document is cited on page 104 of the specification of the present application;

KAYTOR, et al., "Current Opinion of Neurobiology," 2002, Vol. 12, No. 3, page 275-278, Applicants note that this document is cited on page 104 of the specification of the present application;

ELDAR-FINKELMAN, "Trends of Molecular Medicine," 2002, Vol. 8, No. 3, page 126-132, Applicants note that this document is cited on page 104 of the specification of the present application;

HOSHI, et al., "Proceedings of The National Academy of Sciences of the United States of America," 1996, Vol. 93, No. 7, page 2719-2723, Applicants note that this document is cited on page 104 of the specification of the present application;

SATO, et al., "The Journal of Biological Chemistry," 2002, Vol. 277, No. 44, page 42060-42065, Applicants note that this document is cited on page 104 of the specification of the present application;

DOU, et al., "Proceedings of The National Academy of Sciences of the United States of America," 2003, Vol.100, No. 2, page 721-726, Applicants note that this document is cited on page 104 of the specification of the present application;

MAILLIOT, et al., "Annals of The New York Academy of Science," 2000, Vol. 920, page 107-114, Applicants note that this document is cited on page 104 of the specification of the present application;

PHLEL, et al., "Nature," 2003, Vol. 423, No.6938, page 435-439, Applicants note that this document is cited on page 104 of the specification of the present application;

NOBLE, et al., "Neuron," 2003, Vol. 38, No. 4, page 555-565, Applicants note that this document is cited on page 104 of the specification of the present application;

YAMAMOTO, et al., "Chemical and Pharmaceutical Bulletin," 1996, Vol. 44, page 734-745, Applicants note that this document is cited on pages 118-119 of the specification of the present application;

HUNT, et al., "Journal of the Chemical Society," 1956, page 3099-3107, Applicants note that this document is cited on page 124 of the specification of the present application;

ZWAAGSTRA, et al., "European Journal of Medicinal Chemistry," 1996, Vol.31, page 861-874, Applicants note that this document is cited on page 162 of the specification of the present application;

SOUTH, et al., "The Journal of Heterocyclic Chemistry," 1991, Vol. 28, page 1017-1024, Applicants note that this document is cited on page 163 of the specification of the present application;

TAJIKA, "Yakugaku Zasshi: Journal of the Pharmaceutical Society of Japan," 1961, Vol. 81, page 1456-1459, together with partial English language translation of the same. Applicants note that this document is cited on page 165 of the specification of the present application;

OKAMIYA, "Nihon Kagaku Zasshi", 1962, Vol. 83, page 209-211, together with partial English language translation of the same. Applicants note that this document is cited on page 173 of the specification of the present application;

YURA, "Chemical and Pharmaceutical Bulletin," 1962, Vol.10, page 376-382. Applicants note that this document is cited on pages 173-174 of the specification of the present application;

DIEZ-BARRA, "Tetrahedron," 1997, Vol. 53, No. 33, page 11437-11448. Applicants note that this document is cited on pages 177-178 of the specification of the present application;

SHARANIN, "Zhournal Organicheskoi Khimii: Russian Journal of Organic Chemistry," 1980, Vol.16, No. 10, page 2185-2188, together with partial English language translation and Chemical Abstracts. Applicants note that this document is cited on page 183 of the specification of the present application;

HILL, et al., "Cell," 1993, Vol. 73, No. 2, page 395-406, Applicants note that this document is cited on page 194 of the specification of the present application;

European Patent Publication No. EP 1 205 478, which is also the publication for WO 01/10865;

U.S. Patent No. 4,358,443;

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WO 01/98290 together with Japanese family member JP2004-501146 and family member U.S. Patent No. 6,414,013;

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DUMAS, et al., "Bioorganic and Medicinal Chemistry Letters," 1999, Vol. 9, No.17, page 2531-2536;

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UPADHYAY, et al., "Indian Journal of Heterocyclic Chemistry," 1991, Vol. 1, No.,2, page 71-74; and

LADVA, et al., "Indian Journal of Chemistry, Section B," 1996, Vol. 35B, No.10, page 1062-1066.

The Examiner's attention is also directed the following information, which includes commonly assigned U.S. applications:

- U.S. Application No. 10/433,619, to MUTO et al., which published as US2004/0259877 A1 and is cited above;
- U.S. Application No. 10/515,341, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07131, filed June 5, 2003, which published as WO 03/103648 A1 on December 18, 2003;
- U.S. Application No. 10/515,343, to MUTO et al., now published as US2006/0019958 A1, which is the U.S. National Stage of PCT/JP03/07130, filed June 5, 2003, which published as WO 03/103658 A1 on December 18, 2003;
- U.S. Application No. 10/515,623, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07120, filed June 5, 2003, which published as WO 03/103665 A1 on December 18, 2003;
- U.S. Application No. 10/515,342, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07129, filed June 5, 2003, which published as WO 03/103647 A1 on December 18, 2003;

- U.S. Application No. 10/516,294, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07119, filed June 5, 2003, which published as WO 03/103654 A1 on December 18, 2003;
- U.S. Application No. 10/515,622, to MUTO et al., which is the U.S. National Stage of PCT/JP03/07127, filed June 5, 2003, which published as WO 03/103656 A1 on December 18, 2003;
- U.S. Application No. 10/516,292, to MUTO et al., now published as US2006/0014811 A1, which is the U.S. National Stage of PCT/JP03/07121, filed June 5, 2003, which published as WO 03/103655 A1 on December 18, 2003;

BAUD, et al., "Trends in Cell Biology," 2001, Vol. 11, No. 9, page 372-377; CLARK, et al., "Nucleic Acids Research," 1986, Vol. 14, No. 20, page 7897-7914;

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KIM, et al., "The Journal of Clinical Investigation," 2001, Volume 108, No. 3, page 437-446;

KLOSA, "Journal fuer Praktische Chemie," 1964, Volume 25, No.1-2, page 48-55 together with English language Abstract(Chemical Abstract) of the same, Column 4022, paragraph 6-Column 4023;

KOPP, et al., "Science," 1994, Vol. 265, page 956-959;

LEE, et al., "Proceedings of The National Academy of Science of The United States of America," 1998, Vol. 95, No.16, page 9319-9324;

MADAN et al., "Molecular Pharmacology", 2000, Vol. 58, No. 3., pp. 526-534;

MANNA, et al., "The Journal of Immunology," 1999, Vol.162, No. 4, page 2095-2102;

MATSUMOTO, et al., "Bioorganic and Medicinal Chemistry Letters," 2000, Vol. 10, No. 9, page 865-869;

MORI, et al., "Yakugaku Zasshi," 1975, Vol. 95, No. 12, page 1477-1482, together with an English language abstract of the same;

NEDOSPASOV, et al., "Cold Spring Harbor Symposia on Quantitative Biology," 1986, Vol. 51, No.1, page 611-624;

OHSUGI, et al., "Yakugaku Zasshi," 1976, Vol. 96, No. 2, page 165-169, together with an English language abstract of the same;

OKAMOTO, et al., 18<sup>th</sup> Meeting of the Japanese Inflammatory Society, Symposium "Mechanism of Antirheumatic Pharmaceutical composition and New Development," Tokyo, 2000 Presentation Abstract PAGE 57, with English translation;

PALANKI, "Current Medicinal Chemistry," 2002, Volume 9, No. 2, page 219-227;

RÉGNIER, et al., "Cell," 1997, Vol. 90, No.2, page 373-383;

ROBERT-PIESSARD, et al., "Pharmaceutical Science," 1997, Vol. 3, No. 5/6, page 295-299;

SCHEINMAN, et al., "Science," 1995, Vol. 270, page 283-286;

SULLIVAN, et al., "The Journal of Medicinal Chemistry," 1998, Vol. 41, No. 4, page 413-419;

UMEZAWA, "Surgery Frontier," 2002, Vol. 9, No. 2, page 88-91, together with English language translation of the same;

VERMA, et al., "Genes and Development" 1995, Vol. 9 No. 22, page 2723-2735;

WAJANT, "Cellular Signaling," 2001, Vol. 13, No. 6, page 389-400;

WEST, et al., "Analytical Biochemistry," 1990, Volume 190, No. 2, page 254-258;

WORONICZ, et al., "Science," 1997, Vol. 278, page 866-869;

YIN, et al., "Cell," 1998, Vol. 93, No. 5, page 875-884;

YIN, et al., "Nature," 1998, Vol. 396, page 77-80;

YUAN, et al., "Science," 2001, Volume 293, page 1673-1677;

ZANDI, et al., "Cell," 1997, Vol. 91, No.2, page 243-252;

WO 97/09315, together with an English language Abstract of family member of Japanese Patent Publication (KOHYO) HEI 11-0512399 and U.S. family members 5,852,028, 5,811,428 and U.S. 5,935,966;

WO 99/46267, together with an English language Abstract of family member Japanese Patent Publication No. 2002-506072 and U.S. family members:

- U.S. Patent No. 6,225,329;
- U.S. Patent No. 6,262,044;
- U.S. Patent No. 6,410,586;
- U.S. Patent Publication No. 2002/002199 A1;
- U.S. Patent Publication No. 2002/019412 A1;
- U.S. Patent Publication No. 2002/165398 A1;

U.S. Patent Publication No. 2003/069267 A1;

WO 99/55663 together with U.S. family members U.S. Patent No. 6,653,309 and U.S. Patent Publication No. 2004/087650 A1;

WO 00/35442;

WO 01/00213;

WO 01/44217;

WO 01/68648;

WO 02/28819;

European Patent Publication No. EP 0 198 456, together with an English language Abstract of the same;

European Patent Publication No. EP 0 221 346, together with family member Japanese Laid-open Patent Publication No. SHO 62-81359, together with an English language Abstract of the same and U.S. family member U.S. Patent No. 4,939,133;

European Patent Publication No. EP 0 317 991, together with family member Japanese Laid-open Patent Publication No. HEI 2-138260, together with an English language Abstract and U.S. family members U.S. Patent Nos. 4,786,644; 4,952,588 and 4,966,906;

European Patent Publication No. EP 0 452 873, together with family member Japanese Laid-open Patent Publication No. HEI 4-217981 and U.S. family member U.S. Patent No. 5,126,341;

European Patent Publication No. EP 0 551 849, together with family member Japanese Laid-open Patent Publication No. HEI 6-9476 and U.S. family members U.S. Patent Nos. 5,589,514; 5,776,977 and 6,159,988;

European Patent Publication No. EP 1 018 514 together with family member WO 00/05234, together with an English language Abstract of the same and U.S. family member U.S. 6,734,180;

European Patent Publication No. EP 1 088 819, together with family member Japanese Patent Publication No. 2001-114768 and U.S. family members U.S. Patent No. 6,787,652 and U.S. Patent Publication No. 2004/157844 A1;

European Patent Publication No. EP 1 219 596 together with family member WO 01/12588, together with an English language Abstract of the same and U.S. family member U.S. Patent No. 6,566,394;

Japanese Patent Publication No. 2000-80041, together with an English language Abstract of the same;

Japanese Patent Publication No. HEI 9-169747, together with an English language Abstract of the same;

Japanese Patent Publication No. SHO 63-104912, together with an English language Abstract of the same;

Japanese Patent Publication No. HEI 11-21243, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 9-227561, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 10-87491, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 10-45738, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 11-217361, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 8-175990, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. HEI 4-217916, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. SHO 62-30780, together with an English language Abstract of the same and U.S. family members U.S. Patent Nos. 4,659,710 and 4,690,924;

Japanese Laid-open Patent Publication No. 2000-169479, together with an English language Abstract of the same;

Japanese Laid-open Patent Publication No. 52-110835, together with an English language Abstract of the same;

United Kingdom Patent Publication No. GB 1 099 865, together with family member French Patent Publication No. FR 1 481 713;

United Kingdom Patent Publication No. GB 2 031 410; and U.S. Patent No. 3,906,023;

Further to 37 C.F.R. §1.98, copies of the U.S. patents and the co-pending U.S. applications are not enclosed. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicants respectfully request that the Examiner consider the above material and cite the same. Copies of the above-noted foreign documents and articles are attached hereto and all of the documents are listed on the attached PTO-1449 Form. The Examiner is requested to initial the appropriate spaces on the attached Form and to return a copy of the initialed Form to Applicants with the next official communication in the present application.

Applicants note that an Office Action on the merits has not issued in the present application, and thus no fee is believed necessary to ensure consideration of the submitted material. However, if any fee is necessary for consideration of this Information Disclosure Statement, the undersigned hereby authorizes the charging of any fee necessary for the consideration of this

statement, including any payment under 37 C.F.R. §1.17 (p), to Deposit Account No. 19-0089.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted, Susumu Mila O et al.,

Bruce H. Bernstein Reg. No. 29,027

February 15, 2006 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191 Arnold Turk Reg. No. 33094

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U.S. Department of Commerce Patent and Trademark Office Atty. Docket No. P26319

Application No. 10/515,293

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

Applicant Susumu MUTO et al.

Filing Date

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U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. P26319

Application No.

INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) Applicant Susumu MUTO et al.

Filing Date June 5, 2003 Group Not Yet Assigned

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U.S. Department of Commerce Patent and Trademark Office

Atty. Docket No. P26319 Application No. 10/515,293

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Applicant Susumu MUTO et al.

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